

REMARKS

Claims 22-24, 27, 32-36, 41, 43-44, 46-47, and 53-58 were pending in the application. Claims 33-36, 41, 43-44, 46-47, and 54 have been withdrawn from further prosecution as drawn to non-elected groups. Claims 22, 23, 24, 27, 53, 55, 56, 57, and 58 have been amended and new claims 59-73 have been added. Accordingly, upon entry of the present amendment, claims 22-24, 27, 32, 41, 53, and 55-73 will be pending in the instant application.

Support for the amendments to the claims may be found throughout the specification and claims, as originally filed. *No new matter has been added.*

Any amendments to and/or cancellation of the claims are not to be construed as an acquiescence to any of the rejections set forth in the instant Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the subject matter of the claims as originally filed in this or a separate application(s).

Rejection of Claim 53 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claim 53 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that “claim [53] is confusing because when each of k, m, t, p and q are zero, the variables W, A, C and Y are not present and the structure is moot. In this case, claim 53 is not claiming anything. Further, the variable q and m are in conflict when m is zero and q is 1. If m is 0, the nitrogen substituent, which is directly bonded to A, can not be present. In this case, if m is zero, then the value of q is also zero by definition.” Applicants respectfully disagree.

Applicants respectfully submit that claim 53 fully complies with 35 U.S.C. §112, second paragraph. “The primary purpose of this requirement ... is to ensure that the scope of claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent.” MPEP 2173. Definiteness is to be analyzed not in the vacuum but in light of the instant specification, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

MPEP 2173.02. Applicants submit that a person of ordinary skill in the art would immediately understand the scope of claim 53, at least because the recited formula employs common methods of representing chemical structures.

Specifically, a person of ordinary skill in the art would know that when each of k, m, t, p and q are zero, the variables W, A, C and Y, respectively, are not present. Such an interpretation does not render the structure moot: Only if k, m, t, p, q and n were zero, would there be no structure represented, however, a person of ordinary skill in art would know from claim 53, that this eventuality is not claimed for this very reason. That is a person of ordinary skill in the art would immediately understand that claim 53 includes a compound defined by the recited structure. Moreover, the variables q and m are not in conflict when m is zero, because a person of ordinary skill would immediately understand what the Office Action itself points out: “[i]n this case, if m is zero, then the value of q is also zero by definition.”

“Claims to chemical compounds and compositions containing chemical compounds often use formulas that depict the chemical structure of the compound. These structures should not be considered indefinite nor speculative in the absence of evidence that the assigned formula is in error.” MPEP 2173(t). Accordingly, and for at least the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claim 35 under 35 U.S.C. §112, second paragraph.

Rejection of Claims 22-24, 27, 53, and 55-57 Under 35 U.S.C. §102

Claims 22-24, 27, 53, and 55-57 have been rejected under 35 U.S.C. §102(b) as being anticipated by Cik, *et al.* (*Biochem. J.* (1993) 296:877-893). Specifically, the Examiner states that “Cik, *et al.* disclose that cloned N-methyl-d-aspartate subunits can be expressed *in vitro* in HEK 293 (human embryo kidney) cells, as in claims 55 and 56. Cik, *et al.* teach that the inclusion of 2-amino-5-phosphopentanoic acid (AP5), as in claims 27 in the culture medium increases the expression of the subunits in the cells, as in claim 24. 2-Amino-5-phosphopentanoic acid (AP5) is a synonym of 2-Amino-5-phosphonovaleric acid, specie ii of instant claim 27. AP5 also meets the structural limitations of the generic claims 53 (abstract).”

Applicants have carefully considered the Examiner's comments and have amended independent claim 22 to more particularly point out and distinctly claim the invention recited in claim 22. Claim 22, as amended, is not anticipated by Cik, *et al.*, at least because Cik, *et al.* fails to disclose or teach a method for the preparation of cells suitable for treating a subject having a disease in which amyloid deposits are present.

Therefore, since Cik, *et al.* fail to teach each and every element of the claimed invention, this reference cannot anticipate the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir.1987). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 22-24, 27, 53, and 55-57 under 35 U.S.C. §102(b).

Rejection of Claims 22-24, 27, 53, and 55-58 Under 35 U.S.C. §103(a)

The Examiner has rejected claims 22-24, 27, 53, and 55-58 as being unpatentable over Westermarck (Westermarck, *et al.*, *Amyloid and Amyloidosis* 1998, Pros. Int. Symp. Amyloidosis, 8th, Rochester, Minn), in view of Copani (Copani, *et al.*, 1995 *Mol Pharm* 47:890) and Kisilevsky (Kisilevsky, 1996 *Drugs and Aging* 8:75). Specifically, the Examiner states that

[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to add serine-O-phosphate to human islets intended for transplantation in order to inhibit amyloid deposits in islets. The ordinary artisan would have been motivated to do so because serine-O-phosphate had been shown to inhibit the deposition of β AP in kidney cells. The ordinary artisan would have had a reasonable expectation of success that serine-O-phosphate would inhibit or remove IAPP deposits in islet cells because all amyloid-based diseases have common components that would be susceptible to the same types of amyloid-inhibiting treatments.

Applicants disagree, and respectfully request that the Examiner reconsider and withdraw this rejection for the following reasons.

Westermarck teaches the development of a mouse model to study IAPP amyloid deposition in humans, however the authors are unable to reconcile or explain the differences in the formation of amyloid deposits between transgenic mice expressing human IAPP and normal mice with implanted islets. Westermarck indicates that the models studied do not accurately

model human IAPP amyloid deposit formation, and conclude that the mechanism “is more complex than previously believed.”

As the Office Action states, Westermarck does not disclose contacting human islets with a compound that inhibits amyloid deposits in human islet cells. Accordingly, Westermarck is deficient at least because it does not teach or suggest contacting cells *in vitro* with an inhibitor of amyloid deposit formation. In addition, Westermarck does not disclose cells suitable for treating a subject having a disease in which deposits are present.

The teachings of Copani and Kisilevsky fail to make up for the deficiencies of Westermarck. Copani, teach that co-incubation of serine-O-phosphate or 2-amino-4-phosphobutanoate with bAP in culture protect neural cells from amyloid induced apoptosis. They do not teach whether amyloid is inhibited or destroyed, only that apoptosis is modulated, *i.e.*, Copani, et al. do not teach contacting cells with an inhibitor of amyloid deposit formation. Furthermore, like Westermarck, Copani fails to teach or disclose the preparation of cells suitable for treating a subject having a disease in which amyloid deposits are present, as is presently claimed.

In addition, Copani fails to teach or disclose the preparation of cells suitable for treating a subject having a disease in which amyloid deposits are present, as is presently claimed. Similarly, Kisilevsky fails to teach or suggest methods for the preparation of cells suitable for treating a subject having a disease in which amyloid deposits are present.

In sum, the references fail to establish a *prima facie* case of obviousness, at least because, the prior art references, alone or in proper combination, fail to teach or suggest all of the claim limitations. Moreover, there would have been no motivation to combine the teachings of the cited references in the proposed manner to arrive at the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection of claims 22-24, 27, 53, and 55-58 under 35 U.S.C. §103(a).


CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this statement. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. NBI-108US from which the undersigned is authorized to draw.

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Respectfully submitted,

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